UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

PATRICIA LAUCELLA et al., Plaintiffs, v. MEDTRONIC, INC. et al., Defendants.	Case No. 2:25-cv-00466-SB-PVC ORDER DENYING MOTION TO REMAND [DKT. NO. 36], GRANTING MEDTRONIC, INC.'S MOTION TO DISMISS [DKT. NO. 42], AND DENYING AS MOOT DR. MEAD'S MOTION TO DISMISS [DKT. NO. 43]

Erik Lomis died of heart failure after his implantable cardioverter defibrillator (ICD) allegedly malfunctioned, failing to deliver the shocks it was designed to provide. Lomis's widow and daughters filed this products liability action in state court against the ICD's manufacturer, Medtronic, Inc., and two individual California residents: Kyle Spears, a technical consultant, and Dr. Hardwin Mead, a medical doctor on Medtronic's Independent Physician Quality Panel. Defendants removed the case, claiming that Spears and Dr. Mead had been fraudulently joined to defeat diversity. Plaintiffs then filed a First Amended Complaint (FAC) that dropped the claims against Spears and expanded the allegations against Medtronic and Dr. Mead. Plaintiffs now move to remand, and Defendants move to dismiss the FAC for failure to state a claim. The Court held a hearing on April 4, 2025, at which both sides submitted on its tentative ruling. Because Defendants have shown that Plaintiffs have no possibility of recovering from Dr. Mead, the motion to remand is denied, and Dr. Mead is dismissed as fraudulently joined. The Court grants Medtronic's motion to dismiss but will allow Plaintiffs leave to amend.

I.

Lomis was implanted with his ICD—a Medtronic Evera XT DR DDBB1D4 ICD (the Implant)—in August 2014. Dkt. No. 33 ¶ 49 (FAC). The Implant is a Class III medical device approved by the U.S. Food and Drug Administration (FDA) following a premarket approval process pursuant to the Food, Drug, and Cosmetic Act (FDCA). *Id.* ¶ 33. The Implant was designed to deliver full-energy shocks of approximately 36 joules to terminate life-threatening arrhythmias and had a typical battery life of 10 years. *Id.* ¶¶ 49–50. The Implant was also designed to alert doctors when its battery begins to reach the end of its normal service life by triggering a "recommended replacement time" (RRT) status once the battery measures below a certain voltage on three consecutive daily checks, after which it should still remain operational for three more months. *Id.* ¶¶ 51–52.

On March 14, 2023, Lomis's ICD reported about 14 months of remaining battery life, and no RRT alert issued. *Id.* ¶ 54. Only eight days later, on March 22, Lomis went into ventricular fibrillation. *Id.* ¶ 55. The Implant detected the problem and attempted therapy but delivered only about 5.2 joules of energy on the first shock and none on the second—far below the programmed and FDA-approved 36 joules. *Id.* ¶ 56. Without the necessary shocks to correct the ventricular fibrillation, Lomis died. *Id.* ¶ 2.

Subsequent review found that the Implant "had material failures, including delamination and cracks in crucial internal components, signifying nonconformance with FDA-mandated specifications." *Id.* ¶ 57. Plaintiffs contend that the Implant did not adhere to the design, battery, and performance specifications in the FDA's premarket approval, such that its "structural and battery components did not match the precise FDA-approved blueprint or withstand the testing and inspection mandated by current good manufacturing practices (CGMP)." *Id.* ¶ 58. Based on its deviation from the federally imposed specifications, the Implant was allegedly "adulterated" within the meaning of 21 U.S.C. § 351. *Id.* ¶ 59. The FAC alleges that the Implant "was shipped in a defective and unsafe condition" and that the defects would have been identified if Defendant had "applied the requisite validation procedures or final acceptance testing." *Id.* ¶¶ 60–61. Plaintiffs also identify multiple FDA recalls for specific subsets of Evera XT DR DDBB1D4 ICDs. *Id.* ¶¶ 69–76.

Dr. Mead is a California-licensed cardiologist who served on Medtronic's Independent Physician Quality Panel for cardiac rhythm products (the Panel). *Id.* ¶ 12. Dr. Mead allegedly consulted with Medtronic regularly about device

performance data, potential safety advisories, and field notices sent to healthcare professionals. *Id*. The FAC alleges that Medtronic, along with Dr. Mead and other Panel members, annually reviewed performance data for the Evera ICD line and that Dr. Mead's "review and feedback directly influenced the specific recommendations provided to physicians, particularly those in California, on whether to continue implanting the product, what follow-up protocols to adopt, and whether prophylactic device removal or replacement was appropriate." *Id*. ¶ 13. Dr. Mead "personally contributed to or approved the guidance that recommended 'physicians should consider device replacement' only for 'pacemaker-dependent patients or those at higher risk,' while encouraging alternative tactics—like more frequent remote transmissions or magnet checks—for Evera users." *Id*. ¶ 14. Dr. Mead allegedly knew about prior recalls, battery depletion issues, and nonconforming circuit components but "did not urge a comprehensive recall or full transparency with the FDA." *Id*. ¶ 16. Plaintiffs allege that Dr. Mead's opinions "carried substantial weight, influencing Medtronic's level of disclosure and the scope of its corrective actions," and that his role "placed him at the center of decisions about whether, when, and how to warn both physicians and the FDA about critical device failures." *Id*. ¶¶ 17–19.

Plaintiffs filed this action in state court against Medtronic, Dr. Mead, and Kyle Spears, who was alleged to be a senior consultant for Medtronic. Dkt. No. 1-1. Defendants removed based on diversity jurisdiction, alleging that Dr. Mead and Spears—who, like Plaintiffs, are citizens of California—were fraudulently joined to defeat diversity. Defendants attached to their notice of removal declarations from Dr. Mead and Spears about their lack of involvement with Lomis's implant. Dkt. Nos. 1-2, 1-3. Plaintiffs then filed their FAC, dropping their claims against Spears and adding more detailed allegations as to Dr. Mead and Medtronic. The FAC alleges claims for negligence and strict products liability (both for its manufacturing-defect and failure-to-warn theories) and derivative claims for wrongful death and loss of consortium. Plaintiffs now move to remand, Dkt. No. 36, and Defendants move to dismiss the FAC for failure to state a claim, Dkt. Nos. 42, 43.

II.

The Court begins with Plaintiffs' remand motion, as it cannot reach Defendants' challenges to the merits of Plaintiff's claims if it lacks jurisdiction.

A.

Federal courts have subject-matter jurisdiction only over matters authorized by the Constitution and Congress. *Kokkonen v. Guardian Life Ins. Co.*, 511 U.S. 375, 377 (1994). A federal district court has original jurisdiction over a civil action when there is complete diversity of citizenship between the parties and the amount in controversy exceeds $75,000. 28 U.S.C. § 1332(a). Complete diversity means that each plaintiff must be a citizen of a different state than each defendant. *Caterpillar Inc. v. Lewis*, 519 U.S. 61, 68 (1996). However, in assessing diversity, courts "disregard the citizenship of a non-diverse defendant who has been fraudulently joined." *Grancare, LLC v. Thrower*, 889 F.3d 543, 548 (9th Cir. 2019). A removing defendant invoking diversity jurisdiction based on fraudulent joinder bears a "heavy burden" because there is a general presumption against finding fraudulent joinder. *Id*.

Most often, when the parties dispute the propriety of removal based on fraudulent joinder, the focus is on the adequacy of the pleadings, with the court examining both the claims as pleaded and the possibility of amendment to determine whether there is "a *possibility* that a state court would find that the complaint states a cause of action" against the nondiverse defendant. *Id.* at 549 (cleaned up). However, disputes over fraudulent joinder may also be "resolved by 'piercing the pleadings' and considering summary judgment-type evidence such as affidavits and deposition testimony." *Morris v. Princess Cruises, Inc.*, 236 F.3d 1061, 1068 (9th Cir. 2001) (quoting *Cavallini v. State Farm Mutual Auto Ins. Co.*, 44 F.3d 256, 263 (5th Cir. 1995)); *accord Ritchey v. Upjohn Drug Co.*, 139 F.3d 1313, 1318 (9th Cir. 1998) ("The defendant seeking removal to the federal court is entitled to present the facts showing the joinder to be fraudulent.") (quoting *McCabe v. Gen. Foods Corp.*, 811 F.2d 1336, 1339 (9th Cir. 1987)).

B.

Plaintiffs move to remand, arguing that the case was improperly removed and that the FAC alleges facts showing a possibility of recovery against Dr. Mead based on his "integral role in Medtronic's decision-making regarding the warnings, recalls, and risk management of the specific Medtronic ICD device" implanted in Plaintiff. Dkt. No. 36 at 3. Although jurisdiction is evaluated at the time of removal, it is undisputed that the Court may look to the FAC, rather than the original complaint in place when Defendants removed, to determine under *Grancare* whether there is a possibility of recovery against Dr. Mead. There is

also no dispute that the amount in controversy exceeds $75,000, so jurisdiction depends solely on whether Dr. Mead is fraudulently joined.

1.

Although the Court's analysis does not hinge on Plaintiffs' subjective intentions, it is noteworthy that while Plaintiffs deny suing Dr. Mead to defeat diversity, they have not asserted claims against any non-California Panel member. In their reply, Plaintiffs provide an explanation of their decision that raises more questions than it answers. Dkt. No. 57 at 1–3. The Panel had eight members in 2016 and nine members in 2021. Only two of the members are California residents, and Plaintiffs explain that the other Californian, Dr. David Cannom, "was not chosen because he was retired during a major portion of the alleged bad acts." Dkt. No. 57 at 3. Plaintiffs explain that they did not sue other members in part because "most of the other 2021 panel members . . . were not members in 2016." *Id*. at 2–3. But the cited materials show just the opposite (as Plaintiffs acknowledged at the hearing): all eight of the 2016 panel members—including four of the five physicians Plaintiffs identify by name as examples—were still on the panel in 2021, and the only change to the Panel was the addition of Dr. Kevin Wheelan. *Compare* Dkt. No. 36-7 at 4 of 14, *with* Dkt. No. 36-8 at 4 of 6. Moreover, Plaintiffs provide no evidence to support their assertion that none of the other Panel members share Dr. Mead's relevant expertise (despite being on a panel to advise Medtronic on the same subject matter). To the contrary, Dr. Steven Compton, a member of the Panel who is not a California resident, is a coauthor with Dr. Mead on one of the two articles on which Plaintiffs rely to demonstrate that Dr. Mead's expertise sets him apart from everyone else on the Panel. Dkt. No. 58-3 at 1 of 4. Accordingly, while the Court's fraudulent joinder analysis focuses on the possibility of recovery against Dr. Mead rather than on Plaintiffs' reasons for selectively suing him, Plaintiffs' argument that they did not name Dr. Mead merely to defeat diversity are unpersuasive.

2.

Turning to the possibility that Dr. Mead may be liable to Plaintiffs, Defendants rely on evidence (i.e., Dr. Mead's declaration) to challenge the accuracy of Plaintiffs' allegations, rather than focusing on the adequacy of the pleadings. Dr. Mead is a cardiologist who has been a member of the Panel—which consists of physicians who provide independent consulting services to Medtronic—since 2007. Dkt. No. 1-3 ¶¶ 3–4. Dr. Mead has never been employed by Medtronic and has never been a designer, manufacturer, importer, or marketer

of any medical devices, including the Implant. *Id*. ¶¶ 3, 5. The Panel "reviews quality deviations in product performance and provides advice regarding communication to patients and the medical community." *Id*. ¶ 4. Dr. Mead explains in his declaration, however, that his role is limited and that he was not involved with any relevant activity involving the Implant:

> Medtronic does not ask the Panel to provide input on the design, manufacture, labeling, warnings, marketing, distribution, or anything related to bringing a product to market. Nor has Medtronic ever asked me, in any capacity, to provide consultation regarding any of the aforementioned pre-market activities related to any of its medical devices, including the Device at Issue.
>
> Accordingly, I was not involved in any research, design, manufacture, labeling, warnings, marketing, distribution, or any other pre or post-market activity related to the Device at Issue.
>
> In my work with the Panel, I have never provided Medtronic consultation specific to the Device at Issue.
>
> Medtronic directs the Panel in its consultation work. Neither I nor any member of the Panel has the authority or control necessary to direct Medtronic in any activities related to its devices, including the Device at Issue.

Id. ¶¶ 6–9. Dr. Mead also states that he has never provided medical care or consultation to or related to Lomis, nor was he "aware of the possibility of the alleged defect in the Device at Issue" before this lawsuit. *Id*. ¶¶ 12, 14.

3.

Plaintiffs, for their part, paint a very different picture, asserting in their motion that Dr. Mead was "a key contributor" to evaluating performance data, that he "had a direct impact on the decisions that left [Lomis's] ICD in place until it malfunctioned," and that "Dr. Mead's involvement extended far beyond mere tangential or administrative tasks; he directly influenced how—and whether—

Medtronic warned physicians and patients." Dkt. No. 36 at 9–11. These assertions, however, are unsupported by evidence.

To rebut Dr. Mead's declaration, Plaintiffs rely on six documents that they claim prove his direct involvement in the challenged decisions, contrary to his declaration.[1]

First, Plaintiffs produce two letters that Medtronic sent to physicians to warn about defects in specific lots of devices. The first, dated in August 2016, cautioned that a lot of 78 devices, including some Evera ICDs, were "manufactured with a specific subset of circuit components" and "may experience rapid battery depletion due to a low resistance path developing within the circuit component." Dkt. No. 36-2 at 1. The second, dated in March 2018, informed physicians of a voluntary recall of 752 devices including ICDs that "may have undergone a specific sequence of manufacturing processes that could lead to an out-of-specification internal gas environment." Dkt. No. 36-3 at 1. Both letters contain recommendations—including considering removal of the affected devices from high-risk patients—that were provided after "consultation with Medtronic's Independent Physician Quality Panel." Dkt. No. 36-2 at 1; Dkt. No. 36-3 at 1. Neither letter mentions Dr. Mead. While the affected devices listed in the letters include some ICDs that were the same model as Lomis's, his device was not among the specific lots identified in either letter, nor is there any suggestion that his device suffered from the manufacturing problems identified in the letters.

Next, Plaintiffs rely on two notices that appear to have been posted on Medtronic's website. One, dated May 10, 2023, states that Medtronic is informing physicians of "a potential for reduced-energy or no-energy high voltage therapy" in its implantable devices, stating that "Medtronic is aware of 27 devices out of ~816,000 distributed worldwide" that had experienced the problem and that "[i]n consultation with an Independent Physician Quality Panel, we are providing physicians with comprehensive patient management recommendations." Dkt. No. 36-4 at 1. The other provides an October 2024 update to a February 2021 advisory

[1] Plaintiffs' counsel purports to authenticate each exhibit merely by describing it as "a true and correct copy of a document I found while rea[sear]ching the allegations prior to filing the lawsuit." Dkt. No. 36-1 ¶¶ 5–8, 10–11. Although this authentication is inadequate, Defendants do not challenge the authenticity of the documents or oppose judicial notice. The Court grants both sides' unopposed requests for judicial notice.

about a small risk (between 0.16 percent and 0.22 percent) of implanted devices experiencing an earlier-than-expected RRT and includes recommendations "[i]n consultation with our Independent Physician Quality Panel." Dkt. No. 36-5 at 1. Although not clear from the face of the document, it is undisputed that this notice, which mentioned more than 140,000 affected devices, encompassed Lomis's Implant, but that the potential problem identified—an early RRT warning—differs from the issue with Lomis's Implant, which failed without having issued an RRT warning. This notice, like the others, does not mention Dr. Mead.

The final exhibits to Plaintiffs' remand motion are two Medtronic product performance reports, one from 2016 and one from 2021, that include statistics about various Medtronic devices and their performance. Dkt. Nos. 36-7, 36-8. Under "Editorial Staff," each report lists "Independent Physician Quality Panel" with the names of the eight or nine Panel members, including Dr. Mead, along with the "Editor," who appears to be a Medtronic officer. The reports do not describe the involvement, if any, of Dr. Mead or anyone else on the Panel in preparing or reviewing the reports.

Thus, four of the six documents on which Plaintiffs rely do not mention Dr. Mead at all, and the two that list his name include no details about any role he (or any of the other Panel members, each of whom is likewise listed) may have personally played in preparing the reports. Without more, these documents do not demonstrate personal involvement by Dr. Mead in any decisions relevant to Plaintiffs' claims or otherwise contradict his declaration. Plaintiffs have not identified any evidence to support their bald assertions that Dr. Mead "contributed to and reviewed" the reports or "played an active role in preparing" them. Dkt. No. 36 at 8.[2]

[2] In reply, Plaintiffs produce two articles coauthored by Dr. Mead to show his expertise in topics related to the Implant and the fact that he received funding from Medtronic. Dkt. Nos. 58-2, 58-3. But Plaintiffs identify nothing in these articles that directly relates to Lomis's implant or the problems it encountered, let alone that shows that Dr. Mead "served in an integral, hands-on capacity regarding Medtronic's ICD monitoring and patient-risk protocols," as Plaintiffs suggest. Dkt. No. 57 at 2. Nor do they contradict anything in Dr. Mead's declaration. To the extent Plaintiffs rely on the articles to distinguish Dr. Mead's expertise from that of the other Panel members and explain why their decision to selectively sue the one non-retired Californian on the Panel was not contrived to defeat diversity, they overlook that Dr. Compton is also a coauthor on one of the articles.

In sum, nothing in Plaintiffs' evidence contradicts Dr. Mead's sworn testimony that he "was not involved in any research, design, manufacture, labeling, warnings, marketing, distribution, or any other pre or post-market activity related to the Device at Issue" and "never provided Medtronic consultation specific to the Device at Issue." Dkt. No. 1-3 ¶¶ 7–8. Plaintiffs' assertions to the contrary are mere speculation. Moreover, their stated reasons—however dubious—for not suing Dr. Mead's fellow panelists implicitly admit that mere membership on the Panel is insufficient to establish liability, which instead requires a more active role in the challenged decisions. Given the uncontroverted evidence that Dr. Mead was not involved in the design or manufacture of the Implant, provided no consultation specific to the Implant, was uninvolved in any post-market activity relating to the Implant, and lacked authority to direct Medtronic in any activity related to its devices, Plaintiffs have not identified any possible basis for prevailing on any claim against Dr. Mead. Nor have Plaintiffs cited any cases in which any member of a similar advisory panel has been found liable on a negligence or products liability claim based on a product's failure.

C.

Accordingly, Defendants' uncontroverted evidence of Dr. Mead's lack of involvement with the Implant meets their burden of establishing that there is no possibility of recovery against him. Plaintiff's motion to remand is therefore denied. In addition, Dr. Mead is dismissed as fraudulently joined, *see Isaacs v. Broido*, 358 F. App'x 874, 876 (9th Cir. 2009) (noting that "a fraudulent joinder finding compels dismissal of the 'sham defendants'"), and his motion to dismiss for failure to state a claim (Dkt. No. 43) is denied as moot.

III.

Having established that federal jurisdiction is proper, the Court now turns to Medtronic's challenge to the adequacy of the pleadings.

A.

To survive a motion to dismiss under Rule 12(b)(6), a plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim has "facial plausibility" if the facts pleaded "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In

resolving a Rule 12(b)(6) motion, a court must accept all well-pleaded factual allegations as true, but "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice," and courts "are not bound to accept as true a legal conclusion couched as a factual allegation." *Id.* (quoting *Twombly*, 550 U.S. at 555). Assuming the veracity of well-pleaded factual allegations, a court must "determine whether they plausibly give rise to an entitlement to relief." *Id.* at 679. There is no plausibility "where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct." *Id.*

B.

It is undisputed that Plaintiffs' claims for wrongful death and loss of consortium in Counts 4 and 5 rise or fall with the substantive claims in Counts 1–3. *See Lattimore v. Dickey*, 239 Cal. App. 4th 959, 968 (2015) (wrongful death claim requires predicate tort); *LeFiell Mfg. Co. v. Superior Ct.*, 55 Cal. 4th 275, 284–85 (2012) (loss of consortium requires underlying tortious injury to spouse). The parties therefore focus on the viability of Plaintiffs' claims for negligence and strict liability in Counts 1–3. Rather than address the causes of action individually, Medtronic argues that the claims are preempted and that neither of Plaintiffs' central theories of liability—manufacturing defect and failure to warn—is adequately pleaded to escape preemption.

1.

Through the Medical Device Amendments of 1976 (MDA) to the FDCA, the federal government extensively regulates Class III medical devices like the Implant, requiring them to receive premarket approval (PMA) from the FDA. 21 U.S.C. § 360e; *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008) ("[The MDA] swept back some state obligations and imposed a regime of detailed federal oversight."). PMA is a "rigorous" process requiring "what is typically a multivolume application," including all studies and investigations of the device's safety and effectiveness and detailed information about the manufacturing process and controls. *Riegel*, 552 U.S. at 317–18. "The FDA spends an average of 1,200 hours reviewing each application" and grants PMA only after making required findings about the device's safety and effectiveness. *Id*. at 318. "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Id*. at 319.

Except where exempted by the FDA, the MDA expressly preempts any state requirement for covered medical devices "(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a). Although state laws that differ from or add to federal regulations of covered devices are preempted, "the MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA." *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1228 (9th Cir. 2013) (en banc).

Surviving express preemption is not the only hurdle a state law claim involving medical devices must clear. Because the FDCA does not permit private enforcement, a state-law claim that "amounts to an attempt to privately enforce the FDCA" is impliedly preempted as inconsistent with federal law. *Perez v. Nidek Co.*, 711 F.3d 1109, 1117, 1119 (9th Cir. 2013). But state law claims that parallel the FDCA's requirements without directly relying on them fall into a "narrow gap" between express and implied preemption: "The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted . . .), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted . . .)." *Id.* at 1120 (quoting *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010)).

2.

Plaintiffs do not dispute this framework but contend that their claims—both for a manufacturing defect and for failure to warn—fall into the narrow gap that allows them to survive preemption. As Medtronic correctly argues, however, Plaintiffs have not adequately alleged violations that fall into that narrow gap. To do so, they "must allege that the defendant violated a particular federal specification referring to the device at issue or identify specific PMA requirements that have been violated." *Erickson v. Bos. Sci. Corp.*, 846 F. Supp. 2d 1085, 1092 (C.D. Cal. 2011) (cleaned up). The fact that a challenged device was included in a product recall does not create a presumption that the device was not manufactured in compliance with the PMA requirements. *Id*. at 1093.

Beginning with the manufacturing defect claim, the FAC identifies a variety of PMA conditions and current good manufacturing practices (CGMPs) for medical devices that Medtronic was required to meet. Dkt. No. 33 ¶¶ 33–48. Plaintiffs also allege that after the Implant malfunctioned, it was found to have "material failures, including delamination and cracks in crucial internal

components, signifying nonconformance with FDA-mandated specifications" and that its "structural and battery components did not match the precise FDA-approved blueprint or withstand the testing and inspection mandated by [CGMPs]." *Id*. ¶¶ 57–58. But Plaintiffs do not allege any facts supporting their assumption that the cracking and other failures observed in 2023 had been present when the Implant was installed in 2014, much less identify which of the numerous cited requirements Defendants are alleged to have violated or identify how the Implant deviated from the blueprint.

Plaintiffs' allegations are insufficient. As the Ninth Circuit has explained, "to survive MDA preemption, a plaintiff cannot simply demonstrate a defect or a malfunction and rely on *res ipsa loquitur* to suggest only that the thing speaks for itself. Instead, for a state law claim to survive express preemption under the MDA, a plaintiff must show that the defendant deviated from a particular pre-market approval or other FDA requirement applicable to the Class III medical device." *Weber v. Allergan, Inc.*, 940 F.3d 1106, 1112 (9th Cir. 2019) (cleaned up) (affirming summary judgment for defendant because evidence of product's defect and malfunction did not establish that the defendant deviated from the FDA's PMA requirements).[3] *Weber* provided an example of what would be sufficiently specific to identify a violation: "if the FDA's pre-market approval 'required 400 degree welds but the manufacturer used a 300 degree welding process,' that could show violation of an FDA requirement and establish a parallel state law claim." *Id*. at 1111 (quoting *In re Medtronic*, 623 F.3d at 1204). Plaintiffs allege no similar failures here; they simply identify numerous requirements to which Medtronic was subject, identify defects at the time of failure, and assume that Medtronic must have failed to comply with some of the requirements nine years earlier. That is exactly the kind of *res ipsa loquitur* reasoning *Weber* prohibits. *See Ebrahimi v. Mentor Worldwide LLC*, 804 F. App'x 871, 872 (9th Cir. 2020) (relying on *Weber* to affirm Rule 12(b)(6) dismissal where plaintiff identified CGMPs and "essentially contend[ed] that the court can plausibly infer that [the

[3] This is because "the FDA's pre-market approval of the process by which a Class III device is manufactured does not guarantee that every device manufactured in that process will work. Rather, the FDA performs a cost-benefit analysis and may approve devices knowing that they sometimes will fail." Weber, 940 F.3d at 1111–12 (cleaned up).

defendant] must have violated at least one of the FDA's CGMPs by not catching her allegedly defective implants").[4]

Nor have Plaintiffs provided adequately specific allegations in support of their failure-to-warn theory. "In states that recognize failure to report claims, such as California, a manufacturer's failure to report adverse events to the FDA can form the basis of a parallel claim that survives preemption." *Sewell v. Mentor Worldwide, LLC*, 847 F. App'x 380, 383 (9th Cir. 2021) (citing *Stengel*, 704 F.3d at 1233; *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 428–29 (2014)). To prevail on such a claim, however, the plaintiff must "allege actual adverse events that [the defendant] did not report to the FDA." *Id*.

The FAC alleges on information and belief that "between 2016 and 2023, Defendants received or became aware of several internal complaints or adverse events—substantially similar to Decedent's device failures—where the Evera™ XT DR DDBB1D4 ICD provided only a fraction of the intended shock energy or no shock at all" and that Medtronic failed to report those adverse events to the FDA as required. Dkt. No. 33 ¶¶ 110–11; *see also id.* ¶ 99 ("Despite knowledge of battery anomalies, circuit defects, and diminished shock output in a portion of the Evera™ XT DR DDBB1D4 ICDs, Defendants failed to adequately inform the FDA of these post-sale adverse events and manufacturing deviations."). These allegations on information and belief of unspecified events during the seven years from 2016 to 2023, while not wholly conclusory, do not state a plausible claim. *See Weaver v. Ethicon, Inc.*, No. 16-CV-257, 2017 WL 680725, at *8 (S.D. Cal. Feb. 21, 2017) (dismissing failure to warn claim as preempted where the complaint did not "present[] specific instances of actual adverse events that Defendant failed to report regarding a failure to absorb"), *aff'd*, 737 F. App'x 315 (9th Cir. 2018); *Grant v. Corin Grp. PLC*, No. 3:15-CV-169, 2016 WL 4447523, at *7 (S.D. Cal. Jan. 15, 2016) (dismissing failure-to-warn claim because "the FAC lacks allegations of actual adverse events that Defendants failed to report, and therefore does not include factual content that would support the causal nexus between these alleged failures and Plaintiff's injuries") (cleaned up); *Hawkins v. Medtronic, Inc.*, No. 1:13-CV-00499, 2014 WL 346622, at *8 (E.D. Cal. Jan. 30, 2014) (dismissing

[4] Plaintiffs cite a single district court decision, *Prudhel v. Endologix, Inc.*, No. 09-CV-0661, 2009 WL 2045559, at *2 (E.D. Cal. July 9, 2009), for the proposition that their more conclusory allegations of CGMP violations are adequate to survive dismissal. *Prudhel* predates the Ninth Circuit's decisions in *Weber* and *Ebrahimi* and is no longer good law to the extent it suggests a different outcome.

claim where complaint generally alleged failure to report adverse events but lacked "any factual content that would support the causal nexus").

Accordingly, Plaintiffs have not adequately (1) alleged how Medtronic violated specific FDA requirements when manufacturing the Implant or (2) identified any specific adverse events that Medtronic was required to report to the FDA and did not report—and that, if reported, would have caused the FDA to act differently and prevented Lomis's death. Absent such allegations, Plaintiffs have not plausibly alleged any claims for violations of state laws that parallel the federal requirements and survive preemption. Plaintiffs' claims are therefore dismissed.

IV.

Plaintiffs request leave to amend in the event the Court finds their claims inadequately pleaded. Dkt. No. 55 at 14. Medtronic has not opposed the request. "The court should freely grant leave [to amend] when justice so requires." Fed. R. Civ. P. 15(a)(2). Although Plaintiffs have already amended their complaint once, this is their first request to amend in response to a pleading challenge. This case is still at an early stage, and Medtronic does not suggest that it would be unfairly prejudiced if Plaintiffs are allowed to amend. Most importantly, it is not evident on this record that amendment would necessarily be futile. Accordingly, the Court grants Plaintiffs' request for leave to amend their claims against Medtronic.

Plaintiffs shall meet and confer with Medtronic by April 7, 2025, to thoroughly discuss their proposed amendment and attempt to resolve or narrow any remaining disputes and avoid the need for further pleading challenges. Plaintiffs shall file their Second Amended Complaint (SAC) no later than April 11, 2025. Medtronic shall answer or otherwise respond to the SAC by April 25, 2025. Plaintiffs are cautioned that if Medtronic moves to dismiss the SAC for failure to state a claim, the Court does not expect to allow Plaintiffs again to amend their pleading to add allegations that could have been included in the SAC. If Medtronic moves to dismiss the SAC, Plaintiffs' opposition shall be due May 5; Medtronic's reply, if any, shall be due May 12; and the motion shall be set for hearing on May 30, 2025 at 8:30 a.m. (the date on which the mandatory scheduling conference will be reset).

V.

Plaintiffs' motion to remand is denied. Their claims against Dr. Mead are dismissed based on fraudulent joinder, and his motion to dismiss is denied as moot.

Medtronic's motion to dismiss is granted, and Plaintiffs' claims against Medtronic are dismissed for failure to state a claim, with leave to amend. If Plaintiffs fail to file their SAC by April 11, 2025, their failure will be deemed an admission that amendment would be futile, and their claims against Medtronic will be dismissed with prejudice.

Date: April 4, 2025

Stanley Blumenfeld, Jr.
United States District Judge